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6/1/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Carlos de la Huerga
Serial No.:	09/833,258
Filed:	April 12, 2001
Title:	Product Labeling Method and Apparatus
Art Unit:	2841
Examiner:	Lindinger, Michael L.
Our Ref.:	250591.90295

Assistant Commissioner for Patents
Washington DC 20231

Box: Amendment

Dear Sir:

In response to the Patent Office Action dated April 10, 2003, please amend the above application as follows.

RESPONSE TO OFFICE ACTION

REMARKS

The above referenced Office Action has been carefully reviewed and reconsideration of this application is respectfully requested in view of the above amendments and the following remarks. In the interest of clarity, the paragraph numbers below correspond to the paragraph numbers in the Office Action.

As an initial matter Applicant notes that Applicant filed an information disclosure statement on March 26, 2003 in this case which was before issuance of the first Office Action and therefore, while the Examiner apparently did not review the references when formulating the current Office Action, the Examiner must

consider the references submitted on March 26th without requiring an additional fee. Applicant includes a copy of the 1449 form herewith for the Examiner's convenience (copies of the references were submitted on March 26th).

1. Claims 1 – 158 were rejected as obvious over Maestre in view of Urguhart and Gombrich. Applicant respectfully and strongly traverses this rejection and addresses several of the claims separately below.

Prior to addressing the specific merits of the Office Action, Applicant provides a brief discussion of prior medicant containers and systems used to configure prior medicant containers (i.e., the area of invention related to the present application). Early medicant containers included labels on which medicant information (e.g., type, prescribing physician, consumption instructions, dosage, instructions regarding allergies, etc.) was printed in a human readable format so that a medicant user could easily identify the medicant contained in the container, refresh his/her memory regarding prescribed dosage regimen, identify how to obtain a refill when appropriate, etc. Unfortunately, it has been recognized that, despite these informative labels, often, label instructions are not closely adhered to and mis-medication (e.g., too little or too much) results. Hereinafter these early containers that included only human readable labels will be referred to as "non-enhanced containers"

One way to reduce compliance problems has been to develop "smart" containers that, generally, include some type of enhanced machine readable memory device (e.g., an electronic memory device or some other type of memory device that includes machine readable information). Hereinafter, containers including machine readable information (where the machine readable information is not generally readable via a human) will be referred to as enhanced containers. In the case of enhanced containers, information regarding a medicant can be stored in the enhanced memory device and can be presented to a container user via an interface (e.g., an electronic cap, an electronic tray, a simple illuminated light when medication is to be consumed, etc.) to facilitate compliance.

While enhanced containers have many advantages over conventional containers, costs associated with smart containers and the hardware (e.g. interface

devices where those devices are in addition to the containers) needed to support such systems has remained prohibitively expensive for many applications. Thus, what exists today is a system wherein a relatively small percentage of containers are enhanced and pharmacies must be able to provide both enhanced and non-enhanced containers. In cases where a medicant user does not have hardware (e.g., an interface sensor cap, tray, etc.) required to use an enhanced container, it is preferred to use a non-enhanced container to minimize costs.

A general perusal of the known medical container configuring art (including Maestre, Urquhart and Gombrich as discussed in greater detail below) makes clear that prior references generally assume either a system including all enhanced containers or a system including all non-enhanced containers. This is not surprising as, generally, references that teach smart or enhanced containers typically teach the advantages of smart containers over, and teach away from, non-enhanced containers that only include human readable indicia.

In a system that assumes all containers are enhanced (e.g., containers with some type of machine readable information), there is no need to determine if an enhanced or a non-enhanced container is required to fill a prescription. Instead, because it is assumed that all medicant users have the capability to use enhanced containers, an enhanced container is always automatically provided.

Claims 1 - 52 and 100 - 158

Turning now to the claims, claim 1 is different than the cited references in both form and function. With respect to function, the claim 1 invention is provided to reduce order filling costs by providing a single system for configuring enhanced and non-enhanced containers and by streamlining the process of configuring enhanced and non-enhanced containers. To this end, with respect to form, claim 1 requires, among other things, (1) a processor that uses a descriptor to identify when enhanced data is associated with an order and that causes a writer to write enhanced data to an enhanced device when enhanced data is associated with an order, the (2) processor causing another indicating function to be performed when enhanced data is not associated with an order.

Thus, claim 1 contemplates a system wherein a descriptor is stored with each order that indicates when enhanced data should be included on a container used to fill the order and a system that uses the descriptor to determine when enhanced data should be included and that provides the enhanced data when appropriate. Here, for instance, instead of requiring a pharmacist to determine if and when enhanced data should be included with a container, the system automatically makes the determination and configures appropriately.

In contrast to reducing the costs of filling prescriptions by streamlining the container configuring process, Maestre's function is to facilitate medication consumption compliance (see background generally and col. 6, lines 59 – 68). This functional distinction (compliance versus streamlining container configuration) is important as it leads to differences in form. To this end, compliance rate cannot be increased via a standard non-enhanced device (e.g., a human readable label) and therefore, like other known prior art that teaches enhanced containers, Maestre assumes that enhanced containers are available for all prescriptions to be filled and that all medication consumers use enhanced containers. In a system that assumes all consumers use enhanced devices there is no reason to make a decision regarding whether or not enhanced data should be written to an enhanced device – data is always written to an enhanced device.

More specifically, with respect to form, as recognized by the most recent Office Action, Maestre fails to teach or suggest a reader for reading a descriptor that indicates if enhanced data should be included with a container to fill a prescription (see bottom of page 2 of Office Action).

In addition, Applicant points out Maestre also fails to teach or suggest the existence of a descriptor or that a processor controls a writing process as a function of information in the descriptor. In this regard, Maestre teaches several ways to program an enhanced memory device. Even Maestre's most automated ways of programming an enhanced device require a pharmacist to commence the programming process. In this regard see Maestre's col. 14, lines 7 – 10 where Maestre teaches that a pharmacist enters a programming command after which a host processor commences dosage schedule programming, col. 17, lines 21 – 24

where Maestre teaches that the programming command must be entered by the pharmacist and similar teachings throughout the specification.

In summary, Maestre fails to teach or suggest a descriptor of the type required by claim 1 (i.e., that indicates whether or not enhanced data is required), reading the descriptor and controlling data writing as a function of the descriptor information.

Turning to Urquhart, the function of Urquhart is to generate and store records related to consumption events and hence is different than the claim 1 function (i.e., to streamline container configuration). With respect to form, Urquhart facilitates record generation by providing an enhanced medicant container that can electronically sense a medicant dispensing event and generate an associated record. While Urquhart's enhanced device on Urquhart's container clearly has to be programmed in some way, Urquhart does not teach much about how the device is programmed. Thus, it is not surprising that, after a perusal of Urquhart, Applicant was unable to identify any teachings regarding a configuring system, much less a system that has the limitations required by claim 1. Generally, Urquhart does not teach or suggest a configuring apparatus for configuring an indicating configuration. More specifically, Urquhart does not teach the claim 1 limitations that Maestre lacks including a descriptor that indicates if enhanced data should be included with a container, a descriptor reader or a processor that operates as a function of the descriptor.

Turning to Gombrich, the function of Gombrich is also to increase medication consumption compliance and therefore is different than the configuration streamlining process of claim 1.

With respect to form, Gombrich teaches a system wherein enhanced data (e.g., a bar code or other electronically stored information) is stored on a patient wristband and similarly formatted information is stored on medication containers and other items so that a code reader can obtain the information from the wristband and medication containers to correlate medications and the like with specific patients (see Gombrich's Abstract and col. 8, line 66 – col. 9, line 7). In Gombrich, if a medication container did not include enhanced machine readable information, Gombrich's invention would not operate and therefore, like other references that

facilitate compliance, Gombrich contemplates that every container and every order filled will be filled in a container including an enhanced device of some type.

While Gombrich does teach a printer (see 46 in Fig. 1) for printing bar codes and the like, Gombrich contemplates a system where the printer always provides bar codes for medication containers (see col. 8, lines 31 – 34 "hospital items including drugs... will include a label 47 with an item identification bar code 49 attached thereto"). Again, as discussed above, here, where all containers include enhanced data, there is no reason to provide a descriptor that indicates whether or not enhanced data should be provided for a container. Thus, not surprisingly, Gombrich fails to teach or suggest a descriptor as required by claim 1, a reader of the descriptor or a processor that operates as a function of the descriptor to provide or not provide enhanced data for a specific container indicating configuration.

Thus, because none of Maestre, Gombrich and Urquhart teaches or suggests a descriptor, reading the descriptor and then either writing enhanced data or not writing enhanced data as a function of the descriptor information, even when taken together the references cannot render claim 1 obvious. For at least the reasons above Applicant believes claim 1 and claims dependent therefrom are patently distinct over the cited references.

Regarding claim 6, that claim further limits claim 1 by requiring that at least some of the descriptors indicate that no data should be written to an enhanced device and wherein the another function includes disabling the writer when no data is to be written to the enhanced device. Again, Applicant points out that each of the cited references contemplates only containers including enhanced data of some type – the enhanced data is required to facilitate compliance or record generation in each of the references. Where all containers must include enhanced data for an invention to work for its intended purpose it would make no sense to provide some containers that do not include enhanced data as required by claim 6. Similar comments are applicable to claim 8.

With respect to claim 7, none of the references cited appears to contemplate a container source controlled by the processor where the source provides containers with enhanced devices attached thereto as required by claim 7. In this regard Maestre teaches a system where enhanced devices have to be manually attached to

containers associated therewith. Similarly, Gombrich teaches that bar code labels are attached when an item is "made" (see col. 8, lines 35 – 39) (where the term made, in the context of a prescription, means when the prescription is filled). While Urquhart teaches a container with an enhanced device, it is unclear what the source of the containers is and there clearly is no teaching that a processor that controls the enhanced data writing process also controls the container source.

With respect to claim 9, because each of the cited references contemplates only enhanced containers, it is not surprising that none of the references teaches a system including a non-enhanced container source or a selection process between enhanced and non-enhanced containers as required by claim 9. Similar comments are applicable to claim 18.

With respect to claim 10, none of the references appears to teach or suggest an enhanced device source and a device attacher for configuring containers that include enhanced devices as required by claim 10. In this regard, Maestre teaches that enhanced devices have to be attached manually as does Gombrich (see the printed out label sheet in Gombrich's Fig. 4) while Urquhart appears to teach a system that includes an integrated circuit memory 52 that is integral with the container. Similar comments are applicable to claim 19.

With respect to claim 25, claim 25 further limits claim 1 by requiring that the descriptors be located on the containers. Thus, here, the reader reads a descriptor from a container, the processor uses the descriptor to determine if enhanced data should be provided for the container and thereafter, if enhanced data is required, the processor writes the enhanced data to an enhanced device associated with the container.

Because none of the references cited contemplates a descriptor, none of the references could possibly teach this limitation. Even if any of the references is construed as teaching a descriptor as required by claim 1, none of the references appears to suggest that information from a container is used to determine if enhanced data should be added to the container by an external processor writing to an enhanced device.

Claim 35 requires, among other things, an enhanced container source including attached enhanced devices, a non-enhanced container source, a

processor for determining when an enhanced container is required and providing an enhanced container when an enhanced container is required wherein the processor also provides enhanced data when required. As indicated above, none of the references contemplates a non-enhanced container and therefore none of the references could possibly contemplate a system including a non-enhanced container source or a processor that determines when an enhanced container is required.

With respect to claim 40, claim 40 requires a descriptor on a label that indicates data to be written to an enhanced device. As indicated above, none of the references cited teaches a descriptor of this type generally or, more specifically, on a label attached to a container.

With respect to claim 42, that claim is drawn to a system for identifying and storing a record of medicant users that use interactive systems (i.e., systems that read enhanced devices) and subsequently using a processor to automatically determine, via the stored record, when the recipient of an order input via an interface requires an enhanced device. Thus, for instance, a system user may store an indication that John Smith uses an interactive system. Thereafter, when a physician indicates that a prescription is for John Smith, the processor automatically determines that an enhanced device is to be included with the container. When an enhanced device is required, the processor indicates so to a configuring system.

Not to belabor the point but, as indicated above, none of the references cited contemplates non-enhanced containers and therefore, as one would expect, none of the references appears to suggest a system for indicating or storing indications regarding whether or not medicant users use enhanced containers or a processor that employs anything akin to such an indication.

With respect to claim 46, claim 46 requires an indicator including a descriptor on a container that includes a first segment with human readable indicia and a second machine readable segment useable to determine if an enhanced device including data should be provided on the container. For instance, the indicator may include a label including standard medication information and also include a bar code where the code indicates that an enhanced device is required for the container.

None of the references cited appears to contemplate an indicator including both human readable indicia and a machine readable segment that indicates that an enhanced device is required.

Claim 48 is drawn to a system for selecting a container type as a function of the area required to provide label information on a container. For instance, on one hand, where a small amount of label information area is required the system may identify a relatively small container for packaging a first item. On the other hand, where a large amount of label information area is required the system may identify a relatively large container for packaging the first item.

Consistent with the above comments, claim 48 requires, among other things, an input device for specifying information about a product to be stored in a container, the product information including label information to be provided on the container exterior, the label information requiring a specific surface area on the container exterior, a processor for determining a container type based on required surface area and an output device indicating container type.

Perusing the cited references, it appears as though neither of Maestre and Urquhart teaches or suggests a label and that, generally, neither of those references discusses various container sizes or selecting container sizes based on any type of information, much less based on the area required for label information. Gombrich appears to contemplate different container sizes but does not discuss selection of containers as a function of labeling requirements. In fact it should be noted that Gombrich's only illustration of a labeled container (Fig. 2) shows a container that is far larger than required to accommodate an attached label. Thus, for at least these reasons Applicant believes claim 48 and claims dependent therefrom are patently distinct over the cited references.

Claim 50 further limits claim 48 by requiring that the information to be included on the label includes product type and quantity and wherein the processor determines a required container volume based on the product type and quantity information and, wherein, the processor selects the container type at least in part based on the required volume. Again, none of the cited references appears to teach these limitations – i.e., no reference teaches an automated container selection apparatus generally.

Claim 100 is drawn to a system wherein a sponsor such as a drug manufacturer indicates specific circumstances under which the sponsor will pay for medicant users to use containers including enhanced devices wherein, when a prescription is to be filled, a processor compares prescription information to the circumstances under which sponsorship exists and then indicates whether or not an enhanced container or a non-enhanced container should be provided to fill a prescription.

To this end, claim 100 requires a sponsorship medication profile database indicating sponsorship conditions, an input device for receiving prescription information and a processor that compares the prescription information to the sponsorship conditions and indicates either an enhanced or a non-enhanced container as a function of the comparison.

Nothing in the cited references appears to discuss sponsorship of enhanced device programs and hence a sponsor's database including conditions under which enhanced containers should be provided is not suggested by the references. In addition, again, none of the references suggests non-enhanced containers as an option and therefore a processor that determines what type of container to use to fill an order is absent from the references. Similar comments are applicable to claim 112 which includes similar limitations.

Claim 106 is similar to claim 35 except that instead of including enhanced and non-enhanced container sources, claim 106 includes enhanced and non-enhanced label sources. For the same reasons discussed above with respect to claim 35 Applicant believes that claim 106 is distinct over the cited references.

Claim 108 is drawn to a system for attaching enhanced devices to containers at specific locations with respect to data collectors. More specifically, referring to the present Fig. 1, a container cap 100 includes a member 110 that, when positioned appropriately relative an enhanced device 60 on the container, enables a processor in cap 100 to read information from enhanced device 60. Here, mechanical constraints position member 110 in a specific orientation with respect the external surface of the container. In this and many other cases, proper positioning of enhanced device on the container surface is necessary for member 110 to align with device 60.

Claim 108 covers a system for ensuring that device 60 or other similar devices on other containers is applied to the container in the correct position (e.g., an aligned section) to ensure alignment with member 110.

To this end, claim 108 includes a device attacher and a container positioner where the positioner positions a container relative the attacher such that the aligned section receives an enhanced device when the attacher operates to attach a device. None of the references cited teaches that an enhanced device must be aligned on a specific area of a container to ensure reading of information therefrom by a data collector mechanically constrained when attached to the container. In this regard, each of Maestre and Urquhart teaches a processor device that has a built in memory. Gombrich teaches a bar code that is machine readable but there is no precise location with respect to a container surface on which the bar code must be placed to ensure proper reading by a mechanically constrained data collector.

Claim 130 includes limitations similar to the limitations in claim 1 and therefore, for the reasons discussed above, Applicant believes claim 130 and claims dependent therefrom are patentable over the references cited.

Claim 151 includes limitations similar to the limitations in claim 35 and therefore, for the reasons discussed above, Applicant believes claim 151 and claims dependent therefrom are patentable over the references cited.

Claims 53 - 99

Claim 53 includes limitations similar to those in claim 100 and, for similar reasons, Applicant believes claim 53 is patently distinct over the cited references.

Claim 71 includes limitations similar to the limitations in claim 1 and therefore, for the reasons discussed above, Applicant believes claim 71 and claims dependent therefrom are patentable over the references cited.

Claim 91 includes limitations similar to the limitations in claim 35 and therefore, for the reasons discussed above, Applicant believes claim 91 and claims dependent therefrom are patentable over the references cited.

Claim 97 includes limitations similar to the limitations in claim 42 and therefore, for the reasons discussed above, Applicant believes claim 97 and claims dependent therefrom are patentable over the references cited.

Applicant has introduced no new matter in making the above amendments and antecedent basis exists in the specification and claims as originally filed for each amendment. In view of the above amendments and remarks, Applicant believes claims 1-158 of the present application recite patentable subject matter and allowance of the same is requested. No fee in addition to the fees already authorized in this and accompanying documentation is believed to be required to enter this amendment, however, if an additional fee is required, please charge Deposit Account No. 17-0055 in the amount of the fee.

Respectfully submitted,

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Date: 6-27-03

By: _____

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